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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/633,111	08/04/2000	Jan Carlsson	1614-0238P	2114

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT PAPER NUMBER

1641

DATE MAILED: 02/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/633,111

Applicant(s)

CARLSSON ET AL.

Examiner

Bao-Thuy L. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The amendment dated 12/01/03 has been received. Claims 11-23 have been added. Claims 1-23 are pending.
2. The text of those US codes not found in this office action may be found in a previous office action.
3. All rejections not reiterated herein below are withdrawn in view of the amendment to the claims.

NEW REJECTION

Claim Rejections - 35 USC § 112, second paragraph

4. Claims 8-13, 17, 18, 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite because it is unclear how the membrane or flow matrix has been "adapted" to chromatographically separate each of the two components from one another and from the sample. Has it been treated with some type of reagent or is the make-up of the membrane allows for this to occur. The recitation of "adapted to" without any explanation of how such adaptation occurs does not allows the meets and bounds of the claims to be ascertained.

Claim Rejections - 35 USC § 112, first paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 19-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Newly added claims 19-23 do not have support in the specification as originally filed. The specification only has support for proteins with different isoelectric points. The specification is silent on other components such as peptides, nucleic acids and polynucleotides having different isoelectric points.

REJECTION MAINTAINED

Claim Rejections - 35 USC § 103

7. Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pristoupil for reasons of record in the previous office action, which is reiterated herein below.

Pristoupil discloses the general trends in the development of chromatographic and electrophoretic techniques, and specifically teaches the use of nitrocellulose membrane filters. Pristoupil teaches the use of nitrocellulose membrane having pore size ranging from about 0.01 μm to 10 μm in chromatography and electrophoresis separation of proteins and nucleic acids (pages 109-110). Pristoupil discloses a chamber for membrane chromatography where chromatography in aqueous solutions is performed in a horizontal position (page 112, figure 1). The samples are applied on the

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test strip and after separation; proteins and nucleic acids are visualized by either the sandwich techniques or dyes. Pristoupil discloses that nitrocellulose membranes impregnated with a suitable antigen can be used for the rapid detection, saturation or quantitative determination of specific antibodies in micro amounts of materials (page 119).

Pristoupil differs from the instant invention in failing to specifically state that the polymeric membrane is attached to a liquid-impervious backing. However, Pristoupil teaches the membrane is lay flat on a glass plates in a chromatography chamber; therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the polymeric membrane of Pristoupil by attaching it directly to the glass plates because it is well known in the art that such backing provides the advantage of increased handling strength for the membrane. Pristoupil is considered to make obvious the instant claims because steps f2a through f2c of claim 1; steps f2a-f2c of claim 11; and steps e2a-e2c of claim 12 are seen to be optional.

Pristoupil also differs from the instant invention in failing to specifically recites a membrane comprising the ion-exchange functional groups of claims 1 and 8; however, Pristoupil does specifically teach a membrane having ion-exchange functional and since it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105

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USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980). Since Applicant has not disclosed that the specific limitations recited in instant claims (the specific ion-exchange functional groups) are for any particular purpose or solve any stated problem, and the prior art teaches that nitrocellulose membranes may be impregnated with various ion-exchange functional groups and often vary according to the sample being analyzed and the assay conditions, and that these functional groups can be chosen and altered according to specific needs, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures known in the chromatography art.

Response to Arguments

8. Applicant's arguments filed 01 December 2003 have been fully considered but they are not persuasive.

Applicant argues that Pristoupil does not disclose the invention as claimed. It is the assertion of the Applicant that Figure 1, (reference by examiner as disclosing the invention) does not disclose a flow membrane laying flat on a glass plate, and that the device is a thin hard filter paper or a perforated acetyl cellulose membrane filter fitted to a steel pin. Page 113, first paragraph is asserted by Applicant as teaching the device of Pristoupil, which differs from the claimed invention.

These arguments have been fully considered but are not deemed persuasive. Pristoupil teaches that chromatography is performed in a horizontal position in a simple

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chromatographic chamber made of plexiglass with a simple movable support. Figure 1, page 112. Clearly, the membrane is lay flat on a support surface. The description referenced by Applicant refers to how sample is applied to the membrane, not the membrane itself.

Applicant argues that Pristoupil does not teach ion-exchange chromatography and that the chromatography taught by Pristoupil does not separates each of two components from each and from the sample as they flow along the matrix, rather Pristoupil teaches only the separation of low molecular weight components as a group from the high molecular weight components.

This argument has been fully considered but is not deemed persuasive. Pristoupil teaches that their cellulose membrane contains ion-exchange function, and that there is ionic attraction between proteins of different isoelectric points and the membrane (see page 116, last sentence of 3rd full paragraph through page 117). Pristoupil also teaches that using their method and device, human serum has been fractionated into 8-10 zones detectable by Nigrosine and that this method is useful for characterizing various modified proteins. See page 120, last full paragraph through page 121, lines 1-5. Even though Pristoupil does state that they have not been able to separate more complex mixtures into more than two spots, they do state that they have been able to separate RNA into three individual components. See page 121, 5th full paragraph. Pristoupil also teach that eight ethanol-soluble dyes were separated into in individual components. See page 123, first full paragraph. Therefore, the arguments that Pristoupil does not teach separation of at least two components from each other is not persuasive.

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Applicant argues that Pristoupil does not teach modifying the membrane to add specific ion-exchange groups. This argument has been fully considered but is not deemed persuasive. Pristoupil specifically teaches a membrane having ion-exchange functional groups. And since Applicant has not disclosed that the specific limitation recited in instant claims (the specific ion-exchange functional groups) are for any particular purpose or solve any stated problem and the prior art teaches that nitrocellulose membranes may be impregnated with various ion-exchange functional groups and often vary according to the sample being analyzed and the assay conditions, and that these functional groups can be chosen and altered according to specific needs, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures known in the chromatography art.

The argument that Pristoupil provides no suggestion for modifying the technique disclosed therein to arrive at the instant invention is not persuasive. As stated above, Pristoupil teaches membranes containing ion-exchange functional groups and since such groups are well known in the art, a skilled artisan need only chose the optimal workable conditions and materials through routine experimentation procedures well known in the chromatography art.

Conclusion

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

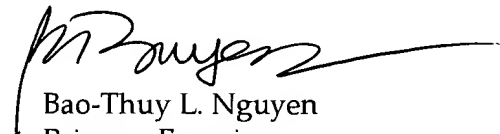
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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 9:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bao-Thuy L. Nguyen
Primary Examiner
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2/12/04